

SCANCELL

AGM presentation

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LSE: SCLP.L



A NEW FRONTIER IN IMMUNO-ONCOLOGY



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DEVELOPMENT PIPELINE

IMMUNOBODY®

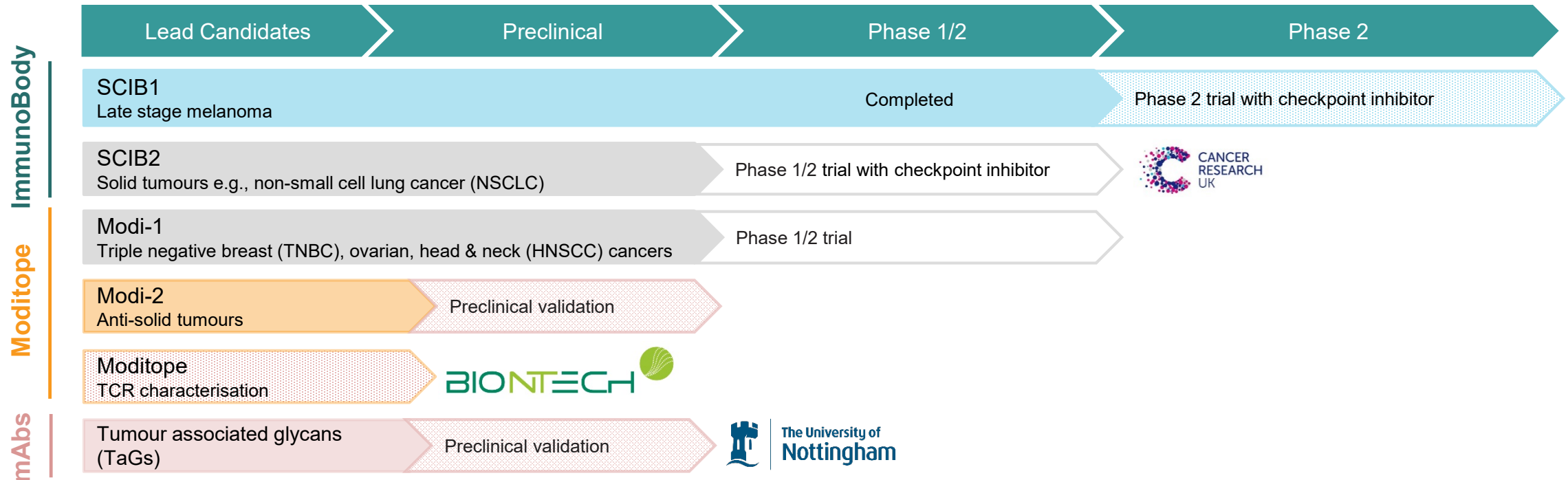
- ▶ **SCIB1:** Targets malignant melanoma. Phase 2 trial in patients receiving immune checkpoint inhibitor
- ▶ **SCIB2:** Targets solid tumours. Phase 1/2 trial with immune checkpoint inhibitor to be funded and sponsored by Cancer Research UK (CRUK)

MODITOPE®

- ▶ **Modi-1:** Phase 1/2 trial including breast, ovarian, and head & neck cancer planned for 1H CY20
- ▶ **Modi-2:** Targets multiple solid tumours
- ▶ **TCR collaboration:** To clone and characterise T cell receptors (TCR) against Modi-1 specific epitopes

AvidiMab™ / TaG mAbs

- ▶ **Anti-glycan mAbs:** Monoclonal antibodies (mAbs) targeting tumour associated glycans (TaGs)
- ▶ **AvidiMab:** Broad potential for enhanced potency of mAbs
- ▶ **Research collaboration:** Evaluation in other platform technologies/formats





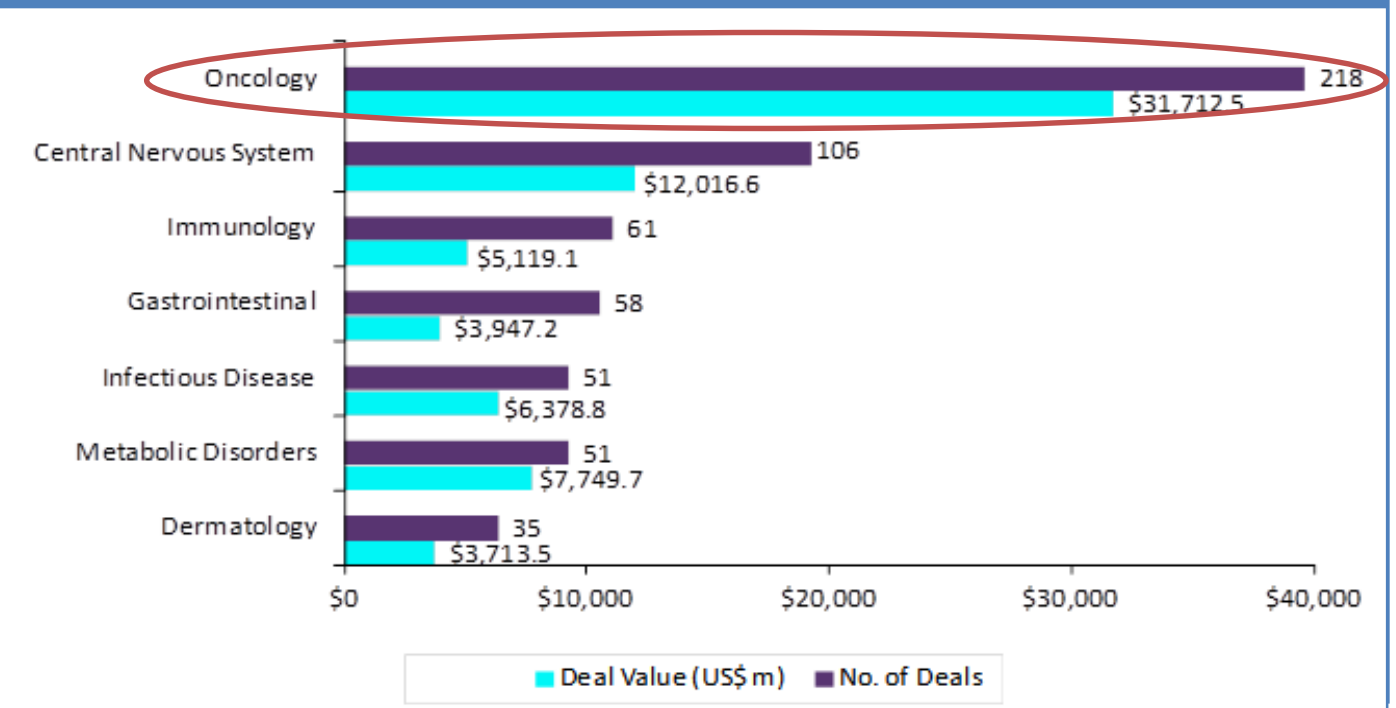
ONCOLOGY PARTNERING TRENDS

- ▶ Drug development is inherently shaped and enabled by strategic partnerships
- ▶ Strategic consolidations provide a significant source of new pipeline drugs for big pharma/biotech companies
- ▶ Pooling resources increase the chances of successfully developing promising candidates, while distributing risks
- ▶ Dedicated resources and processes for identifying strategic partners for licensing or co-development deals

▶ High level of deal-making activity in cancer immunotherapies:

- ▶ Between 2006 and mid-2018 disclosed aggregate licensing/co-development deal value of US\$63.2 billion (circa 64% of deals not disclosed)*
- ▶ A high proportion of disclosed deals were valued at above US\$200m (37%)*
- ▶ US remains most active region for deal making in this sector

Global, Licensing Agreements, by Therapy Area, Number of Deals and Deal Values (US\$ m), 2018

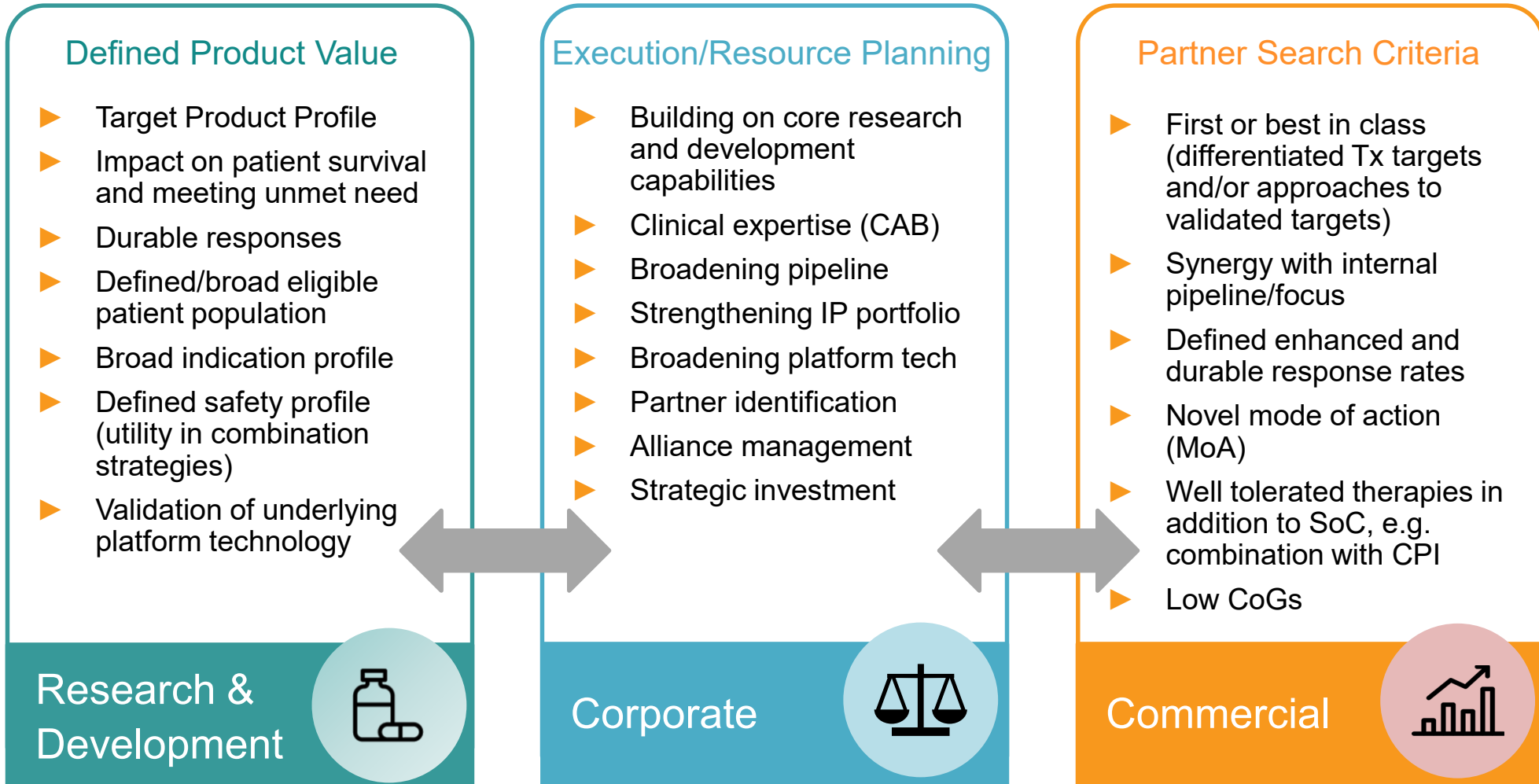


Source: GlobalData, Pharma Intelligence Center, Deals Database - 2018

*Source: GBI Research Global Cancer Immunotherapies Market to 2024 Report, published July 2018



Three Pillars Supporting the Path to Commercial Success





Defining Product Value

- ▶ Phase 1/2 clinical data demonstrates safety and efficacy as monotherapy
- ▶ Phase 2 study initiated (UK)
- ▶ Defined pt population in late stage melanoma
- ▶ Aiming for improved overall response in combination with CPI
- ▶ Durable responses
- ▶ Define safety profile (utility in combination strategies)

Clinical



Enhanced Capabilities

- ▶ Manufacturing expertise
- ▶ Regulatory process
- ▶ Clinical network (CRUK)
- ▶ Project and alliance management
- ▶ Nano-particle delivery tech (SCIB2)
- ▶ Preparation for US based SCIB1 Phase 2 study sites
- ▶ Align assets with companies with existing CPI products

Corporate



Meeting Search Criteria

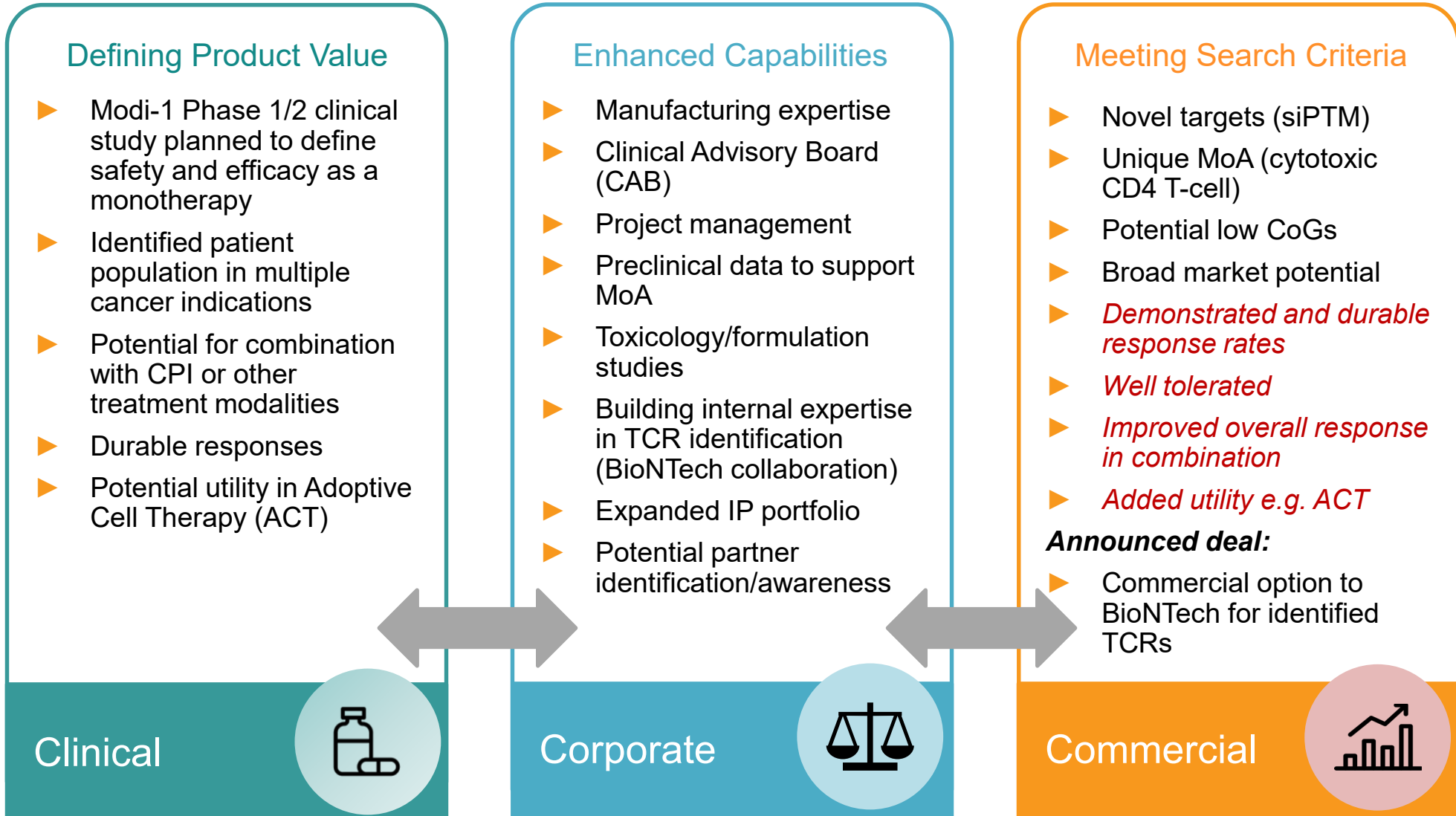
- ▶ Differentiated approach to known antigens
- ▶ Demonstrated MoA
- ▶ Defined durable response rates
- ▶ Well tolerated
- ▶ Potential low CoGs
- ▶ *Improved overall response in combination with an anti PD-1*

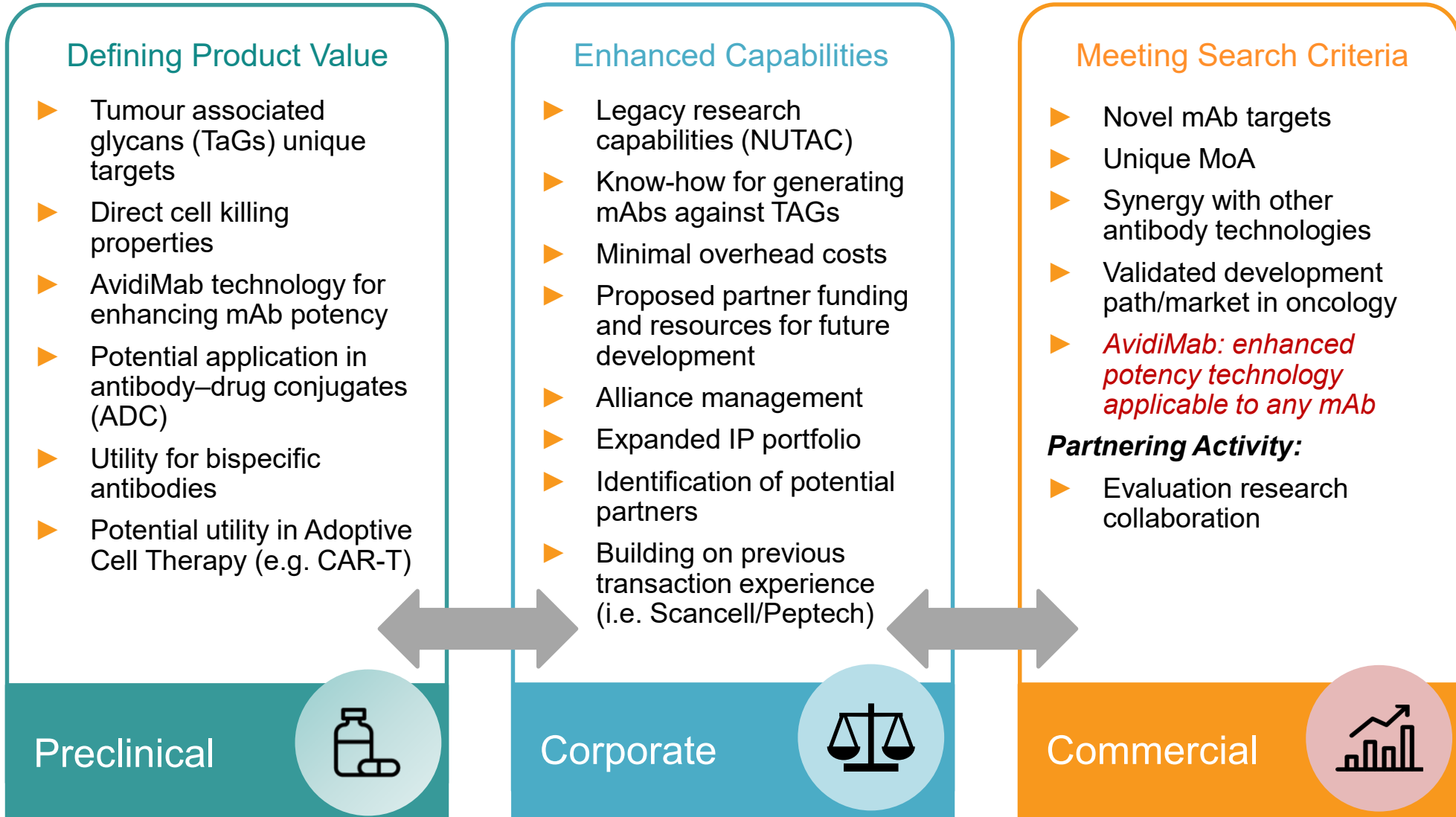
Announced deal:

- ▶ SCIB2 commercial option from CRUK at end of Phase 1/2 study

Commercial









DEVELOPMENT UPDATE





- ▶ Key drivers for initial US vs UK decision
 - ▶ Visibility in US
 - ▶ Enthusiasm of US investigators and availability of patients
 - ▶ Reimbursement of Keytruda costs by US healthcare providers; no equivalent in UK
- ▶ Need open IND **and** UK approval to open a site under an IND in UK
 - ▶ Always intended at least one UK site to do immune response analysis in Scancell labs
 - ▶ Regulatory submissions made in UK to support this
- ▶ IND is **only** for the study drug (SCIB1); cross-refers to Master File for Ichor TDS-IM device
 - ▶ Different FDA divisions review IND (CBER) and MAF (CDRH)
 - ▶ SCIB1-related queries resolved
 - ▶ Ichor TriGrid device query resolution impeded by partial FDA shutdown and communication between CBER and CDRH
 - ▶ Discussions between Ichor and FDA privileged information





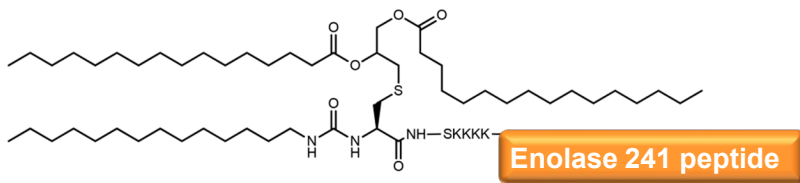
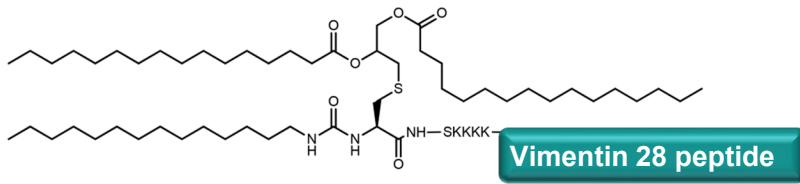
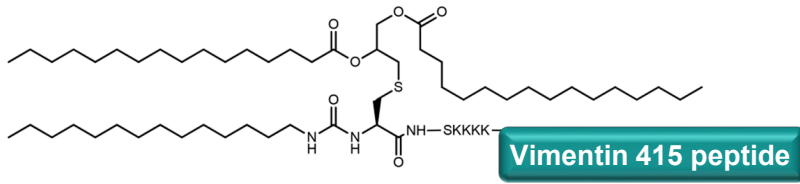
- ▶ UK regulatory submissions approved
 - ▶ MHRA clinical trials division for drug safety
 - ▶ MHRA devices division for TDS-IM device safety
 - ▶ HRA – Health Research Authority for ethics and site approvals
- ▶ Delay in FDA resolution of device issues led to re-evaluation of primary study location
 - ▶ UK approvals obtained (including device)
 - ▶ Agreement from Nottingham NHS Trust to reimburse Keytruda costs
- ▶ **BUT** couldn't open UK site without IND being open
 - ▶ Reluctantly withdrew IND to allow UK site to be activated
 - ▶ Plan to resubmit IND as soon as possible
 - ▶ Option to add US sites (via open IND) to UK trial



SCIB1-002 trial opened for recruitment in UK and actively screening patients



THREE DRUG SUBSTANCES = MODI-1 DRUG PRODUCT



- ▶ Modi-1 conjugates - novel cutting-edge products
- ▶ Hydrophobic peptides
 - ▶ Challenging synthetic properties
 - ▶ Manufacturing
 - ▶ Analytical development



- ▶ Polypeptide Group (PPL) selected as GMP manufacturer for Drug Substances
- ▶ AMRI selected as GMP manufacturer to formulate Drug Product





MODI-1 DEVELOPMENT PROGRESS

- ▶ Development batches of three Drug Substances completed
 - ▶ To supply material for preclinical toxicity and stability studies
 - ▶ Formulation and analytical work
- ▶ GMP manufacture of three Drug Substances ongoing
- ▶ Formulation development underway at AMRI
 - ▶ Soluble formulation identified for each conjugate
 - ▶ GMP manufacturing slot for formulated product secured
- ▶ Analytical assays developed
- ▶ Preclinical toxicity studies in progress
- ▶ Successful regulatory Scientific Advice meeting held at PEI (German equivalent of MHRA); preclinical 'Gold Standard'
- ▶ Request for MHRA Scientific Advice planned Q4 2019 as prelude to Clinical Trial Application for First-in-Human study
- ▶ Clinical Advisory Board meetings held to review and refine clinical trial protocol
- ▶ On target for H1 2020 start for clinical trial





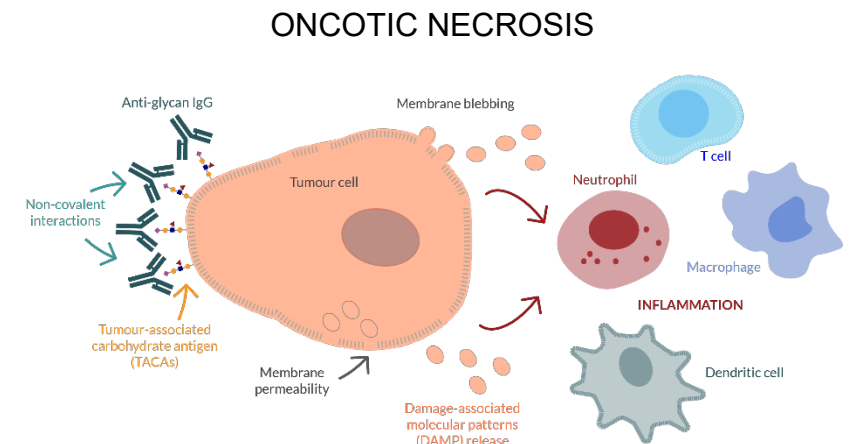
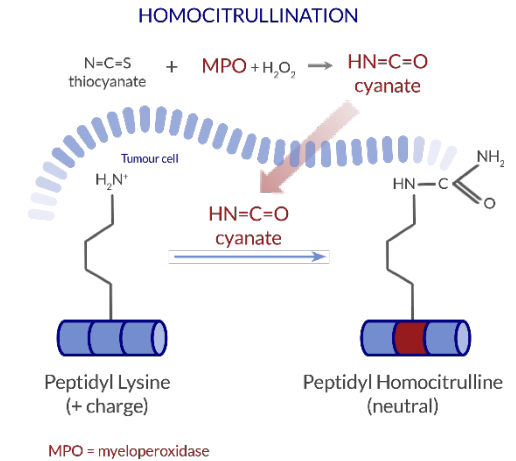
■ ■ ■ ■ **RESEARCH UPDATE** ■ ■ ■ ■



- ▶ **Modi-2: homocitrullination of lysine residues – PCT filed 9-9-19**
 - ▶ Screened 18 peptides using new algorithm
 - ▶ 18 stimulated T cell responses
 - ▶ 5 gave strong anti-tumour responses

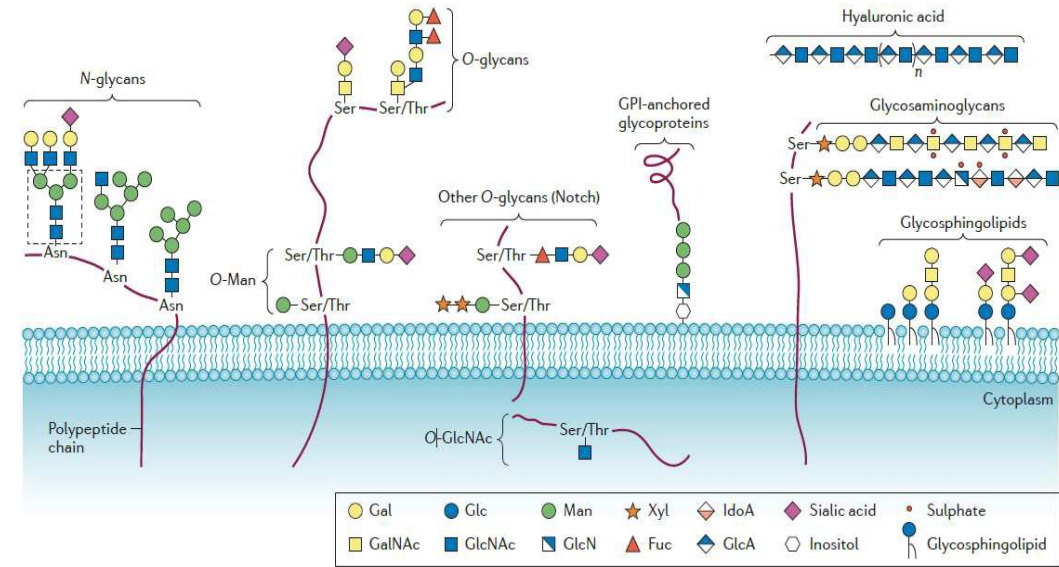
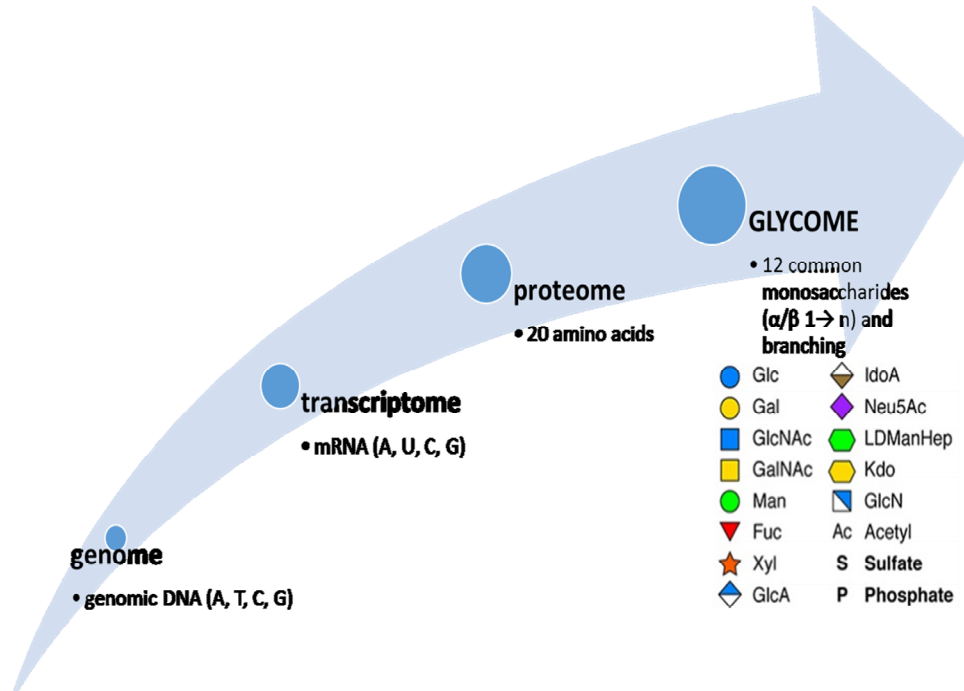
- ▶ **TCR**
 - ▶ Project delayed due to requirement for Health and Safety Approval (HSE)
 - ▶ Lenti-viral transduction of T cells now working in the lab
 - ▶ 40 TCRs recognising citrullinated/homocitrullinated epitopes to screen

- ▶ **Monoclonal antibodies**
 - ▶ Five anti-glycan mAbs and 2 patents in licensed from the University
 - ▶ New platform AvidiMab™ developed to improve the avidity (potency) of any mAb and the direct killing ability of anti-glycan mAbs
 - ▶ Four new patents
 - ▶ Out license to generate revenue for ImmunoBody® and Moditope® platforms





GLYCOME

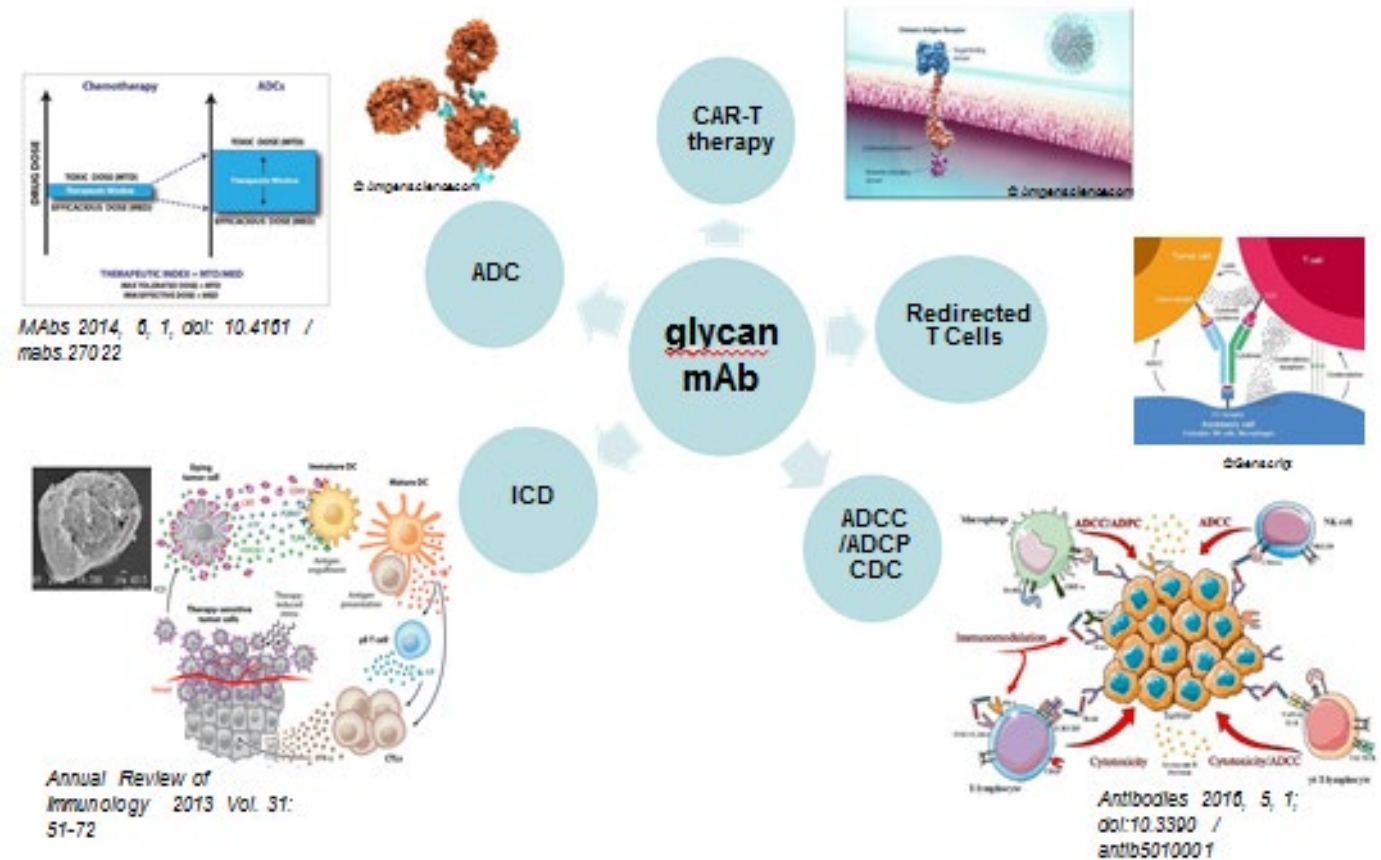


- ▶ Glycans are expressed on a wide variety of molecules
 - ▶ Multiple sugars which can be linked in any order to give a glycan
 - ▶ Sugars can be branched
 - ▶ Sugars are linked by glycosyltransferase enzymes
 - ▶ These enzymes can be up or down regulated in cancer creating unique targets
 - ▶ The same glycan can be expressed on a variety of molecules, giving the mAbs that recognise them multi-functionality



Five new anti-glycan antibodies

- ▶ IgG mAbs with sub-nanomolar functional affinity
- ▶ Ultraspecific to unique tumour-associated glycans (TaGs)
- ▶ Low expression on a limited number of normal tissues
- ▶ Can kill by direct membrane damage
- ▶ Can also induce potent ADCC/ADCP and CDC
- ▶ Can rapidly internalise and are good carriers for drugs
- ▶ Potential to be licensed for redirected T cell and CAR-T therapies

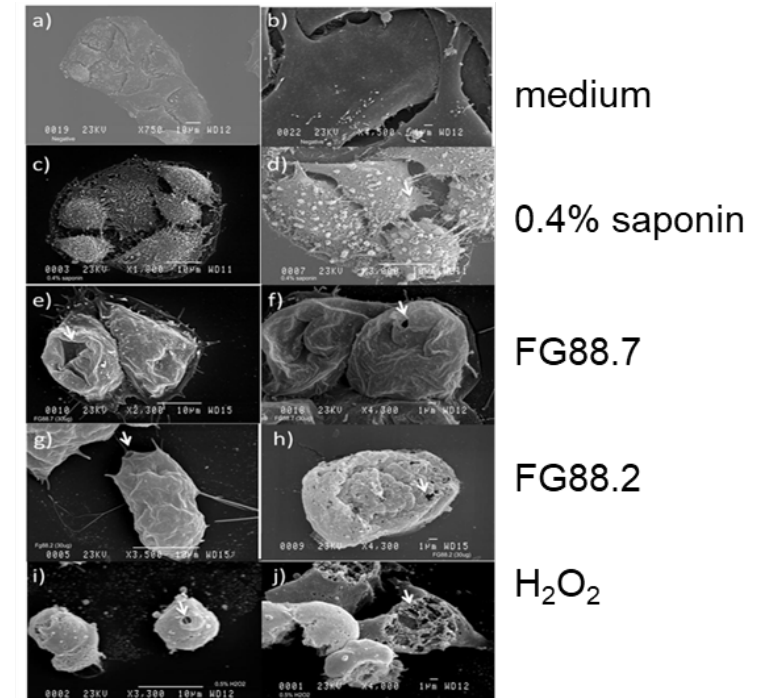
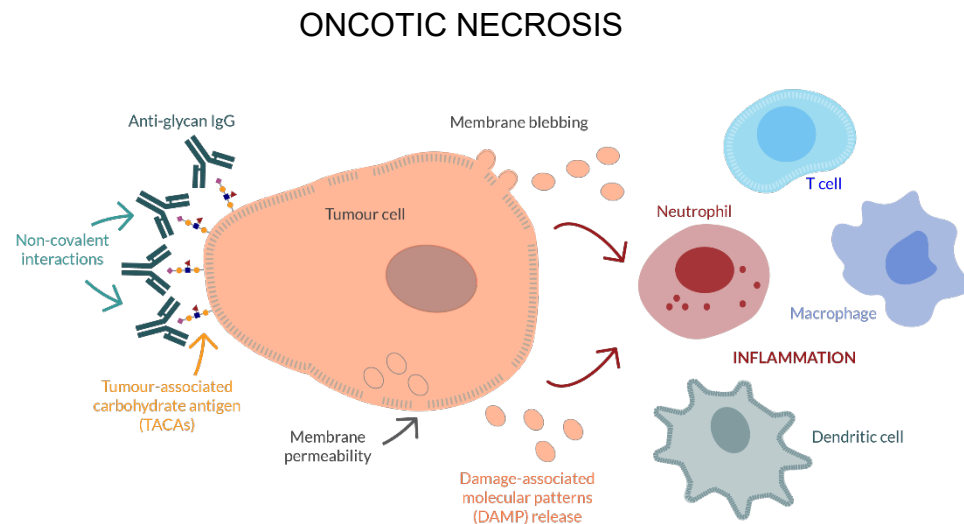


ADCC: antibody-dependent cellular cytotoxicity; ADCP: antibody-dependent cellular phagocytosis; CDC: complement-dependent cytotoxicity; ICD: immunogenic cell death; ADC: antibody drug conjugate; CAR-T: chimeric antigen receptor T-cell



Technology to enhance the avidity of any mAb

- ▶ Non-covalent association at the cell surface
- ▶ Induces direct killing with glycolipid targets
- ▶ Works on cold tumours (no immune response)
- ▶ Does not prevent ADCC/CDC
- ▶ Pharma/Biotechs could license the platform to enhance the potency of their own mAbs



Scanning electron microscope (SEM) analysis of C170 cells incubated with a-b) medium alone, c-d) 0.4% saponin, e-f) FG88.7 (30µg/ml), g-h) FG88.2 (30µg/ml) and i-j) 0.5% H₂O₂ for 20hrs at 37°C. Magnifications are at x2000 (bar= 10µm) and x10,000 (bar= 1µm).